DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; **Notice of Meeting**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 11, 2000, 10 a.m. to 6 p.m.

Location: Marriott Washingtonian Center, Salons C and D, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Megan Moynahan, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8517, ext. 171, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for an intravascular radiation device used in the treatment of instent restenosis.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person

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by September 1, 2000. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:30 a.m. on September 11, 2000. Near the end of committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 1, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: _____8/14/00

August 14, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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